DEPARTMENT OF HEALTH & HUMAN SERVICES



Food and Drug Administration 1401 Rockville Pike Rockville MD 20852-1448

December 28, 1999

Our Reference Number: 97-1215

Mr. Christopher Bentsen Genetic Systems Corporation 6565 185th Avenue NE Redmond, WA 98052-5039

Dear Mr. Bentsen:

This letter is in regard to your Supplement to your Product License Application for Antibody to Hepatitis B Surface Antigen (Mouse Monoclonal) Enzyme-Linked Immunosorbent Assay (ELISA), submitted under section 351 of the Public Health Service Act, to modify the intended use of the Genetic Systems HBsAg EIA 2.0 and the Genetic Systems HBsAg Confirmatory Assay 2.0 to include the testing of cadaveric serum samples.

The Center for Biologics Evaluation and Research has completed the review of this Supplement, and based upon the documentation submitted in support of this request, the Supplement has been found acceptable.

This information will be placed on file with your Product License Application for Antibody to Hepatitis B Surface Antigen.

Sincerely yours,

S. Epstein, M.D.

Director

Office of Blood Research and Review Center for Biologics Evaluation

and Research